IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

BRYAN HUGHES,

Plaintiff,

v. CIVIL ACTION NO. 2:24-cv-00319

CARTIVA, INC.,

Defendant.

ORDER

This discovery matter is before the Court on the *Motion to Compel Discovery Responses from Defendant Cartiva, Inc.*, filed by Plaintiff Bryan Hughes ("Plaintiff"). (ECF No. 24). Therein, Plaintiff seeks an order compelling Defendant Cartiva, Inc. ("Defendant") to serve responses to certain requests for production of documents notwithstanding Defendant's objections to the scope thereof. *See id.* Defendant filed its response in opposition of the motion on December 2, 2024. (ECF No. 34). Plaintiff filed a reply on December 9, 2024. (ECF No. 35). Defendant, with leave of Court, filed its surreply in opposition on December 16, 2024. (ECF No. 55). As such, the motion is ripe for adjudication. For the reasons set forth herein, **IT IS ORDERED** that Plaintiff's motion be **GRANTED IN PART** and **DENIED IN PART**.

I. BACKGROUND

Plaintiff initiated this civil action on June 28, 2024. (ECF No. 1). This is a product-liability case in which Plaintiff alleges injuries stemming from surgical implantation of a Cartiva, Inc. medical device into the first metatarsophalangeal joint of Plaintiff's great toe

on September 11, 2019. The Cartiva, Inc. synthetic cartilage implant ("SCI") is a medical device used to treat great-toe arthritis. According to Defendant, the SCI received approval from the Food and Drug Administration on July 1, 2016. Plaintiff alleges in his *Complaint* that defects in the SCI occurred in the manufacturing process, causing Plaintiff's SCI device to shrink and migrate from the initial site of the implantation. As a result, Plaintiff alleges that he suffered pain, bone loss, and loss of mobility. In support of his product-liability claim against Defendant, Plaintiff alleges, *inter alia*, that Defendant designed and/or manufactured the SCI device in violation of federal law and regulations.

Plaintiff served its *First Set of Discovery* on September 18, 2024. (*See* ECF No. 24 at 2). Although Defendant served its responses to the requests on October 18, 2024, Defendant maintains objections to responding to seven of Plaintiff's requests for production of documents: Request for Production ("RFP") Numbers ("Nos.") 4, 5, 6, 7, 18, 26, and 17. (*See* ECF Nos. 24 at 2-3; 34 at 3). Defendant's objections stem from a fundamental dispute between the parties regarding the appropriate scope of discovery as to other similar incidents involving the SCI at issue in this civil action. Plaintiff, by counsel, asserts that the parties have been unable to reach a resolution of their discovery impasse after appropriately conferring in good faith, both in writing and following a conference call between the parties' counsel. Accordingly, Plaintiff seeks a Court order compelling Defendant to respond to the requests for production of documents, along with attorney's fees and costs in bringing the subject motion to compel. Pursuant to the Court's operative *Scheduling Order*, discovery will conclude on October 10, 2025. (ECF No. 60).

II. LEGAL STANDARD

Rule 26(b)(1) sets forth the scope of discovery under the Federal Rules of Civil Procedure, providing that "[p]arties may obtain discovery regarding any nonprivileged

matter that is relevant to any party's claim or defense and proportional to the needs of the case[.]" Fed. R. Civ. P. 26(b)(1). A party dissatisfied with the opposing party's objections to its discovery request may move for an order to compel discovery or disclosure from an opposing party, after attempting to confer with the party that submitted the incomplete response. Fed. R. Civ. P. 37(a); *Morley v. Energy Serv. of Am. Corp.*, 3:22-cv-00375, 2023 WL 5490189, at *2 (S.D.W. Va. Aug. 24, 2023) (citing Fed. R. Civ. P. 37(a)). Rule 37 of the Federal Rules of Civil Procedure governs motions for an order compelling discovery responses. The Rule provides, in relevant part: [a] party seeking discovery may move for an order compelling an answer, designation, production, or inspection. This motion may be made if: [...] (iii) a party fails to answer an interrogatory submitted under Rule 33; or (iv) a party fails to produce documents or fails to respond that inspection will be permitted—or fails to permit inspection—as requested under Rule 34." Fed. R. Civ. P. 37(a)(3)(B)(iii-iv). "[A]n evasive or incomplete disclosure, answer, or response must be treated as a failure to disclose, answer, or respond." Fed. R. Civ. P. 37(a)(4).

It is well-established that the burden is upon the party resisting discovery, not on the party propounding discovery, to demonstrate *specifically* why the discovery should not be had. *See Slampak v. Nationwide Ins. Co. of Am.*, 5:18-CV-154, 2019 WL 4418806, at *7 (N.D. W. Va. Sept. 16, 2019) (explaining that a party objecting on the basis that a request is overly broad, burdensome, or seeks irrelevant information must "show specifically why responding to the request would create a burden or how the request is overly broad in relation to the claims and defenses presented in the litigation").

The Federal Rules of Civil Procedure confer "substantial discretion . . . in managing discovery" to the federal district court. *Doe v. Cabell Cty. Bd. of Educ.*, 3:21-cv-31, 2022 WL 288193, at *4 (S.D. W. Va. Jan. 31, 2022) (citing *Lone Star Steakhouse & Saloon, Inc.*

v. Alpha of Va., Inc., 43 F.3d 922, 929 (4th Cir. 1995)). Resolution of motions to compel, therefore, are "generally left within the broad discretion of the District Court." *Lone Star*, 43 F.3d at 929. *See also Erdmann v. Preferred Research Inc.*, 852 F.2d 788, 792 (4th Cir. 1988) (noting district court's substantial discretion in resolving motions to compel); *LaRouche v. Nat'l Broad. Co.*, 780 F.2d 1134, 1139 (4th Cir. 1986) (same).

III. DISCUSSION

In support of his motion to compel, Plaintiff argues that information regarding other similar incidents is a fundamental inquiry in medical-device litigation. (ECF No. 24 at 5) (citing *Hershberger v. Ethicon Endo-Surgery, Inc.*, 277 F.R.D. 299, 301-06 (S.D. W. Va. 2011) ("[V]irtually any products liability case asks what happened to the Plaintiff, and whether "this has happened to anybody else")). Relying on *Hershberger*, Plaintiff argues that other similar incidents are clearly relevant, discoverable, and necessary to a Plaintiff's product-liability case, both to show foreseeability and to rebut the manufacturer's defenses. (ECF No. 24 at 6). Further, Plaintiff argues that Defendant's objections are meritless, for a number of reasons. First, Plaintiff points out that "boilerplate" objections are facially meritless, because they fail to address specific merits of the discovery requests; rather, to satisfy its burden as the party resisting discovery, the Defendant is required to provide an affidavit or other evidence to substantiate any claim of burdensomeness. Further, Plaintiff argues that the Defendant's objection to the scope of discovery goes to admissibility, which is relevant to the trial phase, and not discoverability. *See id.* Simply put, Plaintiff asserts that withholding documents based on a unilateral conclusion that the discovery is unrelated was improper, because substantial similarity is an evidentiary standard under the Rules of Evidence, and not the standard during the broader discovery

phase of litigation. *Id.* at 7. Moreover, Plaintiff emphasizes that this information is only in Defendant's hands.

In its response, Defendant asserts that the scope of discovery should be limited temporally, to exclude information "post-dating" Plaintiff's implantation with the device on September 11, 2019, because issues of foreseeability concern Defendant's notice and actions *prior to* Plaintiff's implantation with the SCI device. Likewise, Defendant argues that the scope of discovery should be limited to only those other similar incidents where the alleged failure was attributed to shrinkage and migration of the SCI device—the same failures Plaintiff attributes to his SCI device in this case. (ECF No. 34 at 3-7). Defendant argued that product complaints with no relationship to shrinkage/migration failure—such as errors in packaging, or allergic reactions—were irrelevant. *Id.* at 8. Defendant further argues that the *Hershberger* decision relied upon by Plaintiff is inapposite, because, to the extent the court did comment on other-incident discovery in *Hershberger*, the focus was the defendant's failure to produce information concerning the exact failure mode alleged. *Id.* at 9 (citing *Hershberger*, 277 F.R.D. at 305-06). Defendant argues, therefore, that *Hershberger* does not stand for the proposition that data of the type Plaintiff is demanding—for all other complaints or failures unlimited to those allegedly experienced by this individual Plaintiff, and unlimited in time—is reasonable or appropriate under Rule 26. (ECF No. 34 at 10). Defendant concludes that the discovery at issue is facially overbroad, irrelevant, and should not be compelled in an unrestricted scope. Rather, Defendant argues that "such discovery should be limited . . . to material regarding incidents predating Plaintiff's . . . surgery and concerning the purported defects of device shrinkage and migration[.]" *Id.* Defendant also objects to producing information

related to other similar incidents to the extent it would require turning over confidential patient information protected by HIPAA.

In his reply brief, Plaintiff argues that Defendant's proposed temporal limitation is improper, because evidence of other similar failure incidents *after* Plaintiff's 2019 implantation surgery is relevant to the issues of causation, whether the SCI device is defective, and whether such alleged defect is wide in scope. (ECF No. 35 at 1). Additionally, Plaintiff argues that evidence of other failure incidents—beyond the failure types of migration and shrinkage experienced by the Plaintiff—are probative because this information addresses Plaintiff's allegations in the *Complaint* that Defendant misrepresented its failure rates to the Food and Drug Administration ("FDA") by mislabeling adverse events in an effort to gain and keep FDA approval. (*See* ECF No. 1 at ¶ 108). Plaintiff argues that being forced to limit Defendant's production to only those SCI-device failures *Defendant* labeled as caused by shrinkage/migration "defeats the purpose of Plaintiff's requests, which is to demonstrate that Cartiva mislabeled SCI adverse events and its failure rate due to implant subsidence was much higher than reported." (ECF No. 35 at 2-4). Plaintiff urges the Court that it "should be afforded the opportunity to review all adverse events and prove that those events which Cartiva mislabeled as 'pain' are in fact substantially similar to the defect Plaintiff has alleged." *Id.* at 7.

In its surreply brief, filed with leave of Court, Defendant argues that Plaintiff should not be permitted to use its allegation of mislabeling adverse events as a free pass "to go on a fishing expedition to obtain all of Cartiva's complaint information" with no reasonable limits on the scope of discovery on other similar incidents. (*See* ECF No. 55). In particular, Defendant argues that Plaintiff's mislabeling allegation is meritless, because

"there is not a benefit in labeling events in one category (such as pain) versus any other (such a[s] device shrinking or migration)[.]" *Id.* at 3.

Having reviewed the parties' arguments, the undersigned **FINDS** that Plaintiff is entitled to discovery concerning other similar incidents; however, Defendant's objections to facial overbreadth are sustained in part, requiring reasonable limits on the scope of the discovery sought to "ensure that discovery is sufficient, yet reasonable[.]" *Scott Hutchison Enters., Inc. v. Cranberry Pipeline Corp.*, 3:15-cv-13415, 2016 WL 5219633, at *2 (S.D. W. Va. Sept. 20, 2016) (citing *Seattle Times Co. v. Rhinehart*, 467 U.S. 20, 36 (1984)).

First, with respect to other similar incidents, it is well-established that boilerplate assertions of overbreadth by the party resisting discovery are generally insufficient. *Deitz v. Pilot Travel Centers, LLC*, No. 3:14-cv-31091, 2015 WL 5031229, at *2 (S.D.W. Va. Aug. 25, 2015). With respect to Defendant's argument that the discovery requests at issue are overbroad and overly burdensome, the undersigned agrees with the plaintiff that Defendant failed to meet its obligation to establish this fact. *See id.* Just as the defendant in *Deitz* "did not provide any affidavits or other evidence outlining the anticipated time and resources that would be involved in gathering the information," Defendant in this case has completely failed to set forth any such evidence–including any information "regarding the amount of documentation that would have to be collected and reviewed in order to respond[.]" *See id.* As the Court pointed out in *Deitz*, "many corporations have centralized departments to manage claims and litigation, and with the advent of computers, these corporations would be able to produce the requested information with relative ease." *Id.* Absent any such evidence, the Court rejects Defendant's "boilerplate" objection on such grounds.

Furthermore, the undersigned agrees with Plaintiff that, under West Virginia law, evidence of other similar incidents is fundamental to Plaintiff's case. Simply put, "[i]t is widely-accepted that discovery of other incidents involving the same or similar claims and the same or similar products is permissible in a products liability action." *Edwards v. Arctic Cat, Inc.*, 3:12-cv-03269, 2013 WL 4017152, at *3 (S.D.W. Va. Aug. 6, 2013) (citing *United Oil Co., Inc. v. Parts Assocs., Inc.,* 227 F.R.D. 404, 410-11 (D. Md. 2005)).

The Court previously addressed this issue under similar circumstances in *Edwards*. In that case, Plaintiff brought a product-liability claim against a manufacturer alleging that he sustained physical injuries when a component part in a utility-terrain vehicle failed, causing the vehicle to flip over. *See id.* at *1. A discovery dispute arose in *Edwards* when the defendant manufacturer refused to produce information regarding failures of its off-road vehicles caused by the part at issue—a cast aluminum knuckle. *Id.* Notably, the Court observed in *Edwards* that the plaintiff's discovery extended to "all cast aluminum knuckles used by Defendants in all models of their off-road vehicles." *Id.* The defendant manufacturer argued that the plaintiff was only entitled to information regarding the specific part at issue in the accident, and only as it was used in the specific utility-terrain vehicle involved in the accident. *Id.* at *2. In support of its argument, the defendant in *Edwards* relied on the "substantial similarity" doctrine, pursuant to which "evidence of other incidents may only be discovered when the products involved are the same, the alleged defect is similar, causation in the cases are related to the defect, and all reasonable secondary explanations for the incidents have been excluded." *Id.*

This Court in *Edwards* expressly rejected the defendant manufacturer's position, finding that its "reliance on the 'substantial similarity' doctrine is misplaced because it applies to the admissibility of evidence at trial rather than the relevancy of information

for purposes of discovery." *Id.* (citing *Bennett v. Segway, Inc.,* 1:11–cv–09, 2011 WL 4965179, at *2 (W.D.N.C. Oct. 19, 2011)). The Court explained in *Edwards* that "the demands on the plaintiff are considerably more relaxed in the context of discovery and, clearly, 'the defendant should not be the final arbiter of substantial similarity" for the purposes of determining the scope of a plaintiff's discovery requests.' " *Edwards*, 2013 WL 4017152 at *3 (quoting *Smith v. Gorilla, Inc.,* 10-cv-17, 2010 WL 4286246, at *3 (D. Mont. Oct. 21, 2010)). In light of this relaxed discovery standard, this Court in *Edwards* explained the standard for other similar incidents at the discovery phase. Specifically, "to justify discovery of other incidents, a plaintiff must make only a threshold showing that the other incidents bear some relationship to the issues of notice, the magnitude of the danger involved, the opposing party's ability to correct a known defect; the product's lack of safety for its intended uses . . . standard of care, or causation." *Edwards*, 2013 WL 4017152, at *3 (citing *Desrosiers v. MAG Indus. Automation Sys., LLC,* 675 F.Supp.2d 598, 602 (D.Md.2009)).

Applying this standard to the cast-aluminum knuckle at issue in *Edwards*, this Court found that the plaintiff met its burden to demonstrate that "evidence of other incidents involving the failure of [the] cast aluminum knuckle" had marginal relevancy to Plaintiff's claim that a negligent casting process was used to manufacture the aluminum knuckle used in Plaintiff's vehicle, as it directly pertained to the issues of causation and punitive damages as well as the plaintiff's claims of design and manufacturing defects. *Id.* at *4. Nonetheless, the Court agreed with the defendant manufacturer that "requests seeking information about *any* cast aluminum knuckles and about any other component part" used in any vehicle model made by the manufacturer "is too broad." *Id.* Consequently, the Court in *Edwards* limited the scope of discovery to "information

regarding cast aluminum knuckles" made by the specific manufacturer at issue, and used in the specific vehicle model at issue in the plaintiff's accident. *Id.*

Here, just as in *Edwards*, the undersigned **FINDS** that evidence of other similar incidents is clearly relevant to Plaintiff's defect claims and the issue of causation. Nonetheless, the Court again agrees with Defendant that requests seeking information about every single adverse event is facially overbroad. Plaintiff argues in his reply brief that Defendant mis-labeled adverse events "as 'pain' rather than 'implant subsidence' . . . to avoid the requirements of 21 U.S.C. § 360i[.]" (ECF No. 35 at 4). Plaintiff did not tether any other adverse event, such as errors in packaging, or allergic reactions, to his allegations, sufficiently to justify such a wide swath of discovery under the circumstances. Accordingly, the scope of other-similar incident discovery is hereby limited to those adverse events attributed to pain, implant subsidence, shrinkage, and/or migration.

With respect to Defendant's assertion that the temporal scope of Plaintiff's discovery requests are facially overbroad, the undersigned agrees with Plaintiff that discovery should not be limited to preclude evidence of other similar incidents after the date of Plaintiff's implantation with the SCI device on September 11, 2019. While it is true that this information may not be relevant to the issue of foreseeability, as Defendant asserts, nonetheless it is certainly relevant to the issues of causation and defect. Nonetheless, the undersigned agrees with the Defendant that Plaintiff's RFPs, as written, are "a little broad" as there is no temporal limitation at all. *See Deitz*, 2015 WL 5031229, at *2. Accordingly, while the plaintiff's motion to compel is granted, Defendant shall only be required to provide other-similar-incidents information generated during the time period between July 1, 2016—the date that the SCI device received approval from the Food and Drug Administration on July 1, 2016—through June 28, 2024—the date suit was filed.

Lastly, the undersigned **FINDS** that reasonable protections should be put in place to ensure that the privacy concerns of other patients, and the requirements of HIPAA, 42 U.S.C. § 290d-2, and 89 Fed. Reg. 12472, are protected. The "federal courts . . . respect patients' privacy interests in their medical records and such records generally are not discoverable in a civil action if the person's medical condition is not in issue." *Walker v. Univ. Med. Ctr.*, 2:07-cv-01528, 2009 WL 10693224, at *3 (D. Nev. Nov. 30, 2009). *See also State Farm Mut. Auto. Ins. Co. v. Kugler*, 840 F. Supp. 2d 1323, 1328 (S.D. Fla. 2011) ("Federal courts have long been mindful of preserving confidentiality of medical information"); *Martinez v. Cui*, 06-cv-40029, 2007 WL 9684162, at *5 (D. Mass. Aug. 28, 2007) (explaining that "patients have a privacy interest in their medical records and they expect that the details of their care and treatment are to remain confidential"). Thus, while HIPAA is not a bar to the discovery of patient information when an appropriate HIPAA-compliant protective order is in place, the patient's personally-identifying information generally should be redacted—notwithstanding the protective order—when the patient is a nonparty whose physical condition is not at issue in the civil litigation, unless "the Plaintiff's need for the information vis a vis her claims" outweighs the patient's privacy interest. *See Martinez*, 2007 WL 9684162, at *5. *See also Nw. Mem'l Hosp. v. Ashcroft*, 362 F.3d 923, 927 (7th Cir. 2004). Simply put, "courts throughout the Fourth Circuit, including this Court, have recognized that where, as here, a patient is not a party to an action," redaction of all names and other personally-identifying information of patients is generally appropriate. *Green v. Wilkie*, 2:18-cv-788, 2018 U.S. Dist. LEXIS 243993 (D.S.C. Oct. 19, 2018); *Holt v. Rural Health Servs., Inc.*, 1:21-cv-2802, 2023 U.S. Dist. LEXIS 234554 (D.S.C. June 21, 2023); *U.S. ex rel. Callahan v. U.S. Oncology, Inc.*, 7:00-cv-00350, 2005 U.S. Dist. LEXIS 57465 (W.D. Va. Dec. 16, 2005).

Under the present circumstances, the undersigned **FINDS** that redaction of other patients' names and personal-identifying information, in addition to the protections afforded by the parties' operative *Agreed Protective Order*, is appropriate and sufficient to protect the privacy considerations of these nonparties.

IV. CONCLUSION

In light of the foregoing, **IT IS ORDERED** that Plaintiff's *Motion to Compel Discovery Responses from Defendant Cartiva, Inc.* (ECF No. 24) is hereby **GRANTED IN PART** and **DENIED IN PART**, as set forth above. Defendant is hereby **ORDERED** to serve Plaintiff's counsel with supplemental responses to Plaintiff's RFP Nos. 4, 5, 6, 7, 18, 26, and 17, subject to the limitations in scope as set forth *supra*, by no later than **4:00 p.m. EST** on **Thursday, April 24, 2025**.

IT IS SO ORDERED.

The Clerk of Court is **DIRECTED** to transmit a copy of this Order to counsel of record and to any unrepresented party.

ENTERED: April 2, 2025

Dwane L. Tinsley
United States Magistrate Judge